Supreme Court, U.S.
FILED
AUG 2 2000
CLERK

No. 00-19

In the Supreme Court of the United States

SMITHKLINE BEECHAM CONSUMER HEALTHCARE, L.P.,
Petitioner,

v.

WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., AND CIRCA PHARMACEUTICALS, INC.,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR RESPONDENTS IN OPPOSITION

BARRY S. WHITE
JAMES K. STRONSKI
CHARLES J. RAUBICHECK
DEENA P. LEVY
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, N.Y. 10151
(212) 588-0800

JOSEPH P. LAVELLE
Counsel of Record
MATTHEW J. MOORE
LAURA C. MILLER
HOWREY SIMON ARNOLD & WHITE, LLP
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 783-0800

Attorneys for Respondents

29pp

QUESTION PRESENTED

Whether, in a case of first impression, the Second Circuit properly held that in view of the plain meaning of 21 U.S.C. § 355(j)(2)(A)(v), FDA must require a generic drug to have labeling "the same as" the labeling of the originally approved drug and whether the court therefore properly found that a generic drug manufacturer could not be liable for copyright infringement for following FDA's direction to make its labeling the same as the originator's labeling.

STATEMENT PURSUANT TO RULE 29.6

Pursuant to Rule 29.6 of the Rules of this Court, Respondents Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Circa Pharmaceuticals, Inc. certify that no publicly held entities are parents of Watson Pharmaceuticals, Inc. and/or own 10% or more of Watson Pharmaceuticals, Inc.'s stock.

Respondents Watson Laboratories, Inc. and Circa Pharmaceuticals, Inc. are wholly-owned subsidiaries of respondent Watson Pharmaceuticals, Inc.

TABLE OF CONTENTS

QUESTION PRESENTED i

STATEMENT PURSUANT TO RULE 29.6 ii

STATEMENT OF THE CASE 2

REASONS FOR DENYING THE PETITION 12

CONCLUSION 20

INDEX TO APPENDICES

APPENDIX A 1

TABLE OF AUTHORITIES

CASES

CCC Information Services, Inc. v. MacLean Hunter Market Reports, Inc., 44 F.3d 61 (2d Cir. 1994) 14

Connecticut National Bank v. Germain, 503 U.S. 249 (1992) 15

Davis v. United States, 417 U.S. 333 (1974) 14

Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990) 4

FDA v. Brown & Williamson Tobacco Corp., 120 S. Ct. 1291 (2000) 18

Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562 (Fed. Cir. 1997) 4

Henley v. FDA, 77 F.3d 616 (2d Cir. 1996) 19

Hughes Aircraft Co. v. Jacobson, 525 U.S. 432 (1999) 15

Kordel v. United States, 335 U.S. 345 (1948) 3, 4

Mead Johnson Pharmaceutical Group v. Bowen, 838 F.2d 1332 (D.C. Cir. 1988) 4

Practice Management Information Corp. v. AMA, 121 F.3d 516 (9th Cir. 1997) 14

United States v. Fausto,
484 U.S. 439 (1988) 18

Weinberger v. Hynson, Westcott & Dunning, Inc.,
412 U.S. 609 (1973) 4

STATUTES

21 U.S.C. § 321(m) 3, 4, 5, 15, 18

21 U.S.C. § 355(b)(1)(F) 3

21 U.S.C. § 355(c)(3)(D)(iii) 3

21 U.S.C. § 355(j)(2)(A)(v) ..... passim

REGULATIONS

21 C.F.R. § 202.1(l)(2) 5, 18

21 C.F.R. § 314.94(a)(8)(iv) 4

No. 00-19

In the Supreme Court of the United States

SMITHKLINE BEECHAM CONSUMER HEALTHCARE, L.P.,
Petitioner,

v.

WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., AND CIRCA PHARMACEUTICALS, INC.,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR RESPONDENTS IN OPPOSITION

Respondents Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., and Circa Pharmaceuticals, Inc. (collectively "Watson") hereby oppose the Petition for a Writ of Certiorari to review the judgment of the United States Court of Appeals for the Second Circuit.

STATEMENT OF THE CASE

This is a one-of-a-kind case. It concerns the application of 21 U.S.C. § 355(j)(2)(A)(v), part of the Food, Drug, and Cosmetic Act ("FDA Act"), to an overreaching attempt by SmithKline Beecham Consumer Healthcare, L.P. ("SKB") to use the Copyright Act to prevent generic

competition where Congress has determined that generic competition is in the public interest.

The narrow issue of statutory construction decided by the court of appeals has never arisen in the fifteen-year history of the generic drug laws. The Second Circuit correctly decided the case based on the plain language of the FDA Act. The decision does not conflict with the decisions of this Court or of any other court of appeals. The United States filed an *amicus* brief in the court of appeals and supports the Second Circuit's decision. Certiorari should be denied.

A. Background Of The Dispute

This case arose from SKB's efforts to use a copyright on drug labeling to prevent generic competition for its nicotine gum after SKB's patents and regulatory exclusivity had expired.

For more than fifteen years, SKB maintained a monopoly over the sale of nicotine gum – a drug to help consumers stop smoking – with its proprietary brand Nicorette®. The Food and Drug Administration ("FDA") approved Nicorette as a prescription drug in 1984. (Pet. 6). SKB originally introduced Nicorette as a prescription drug. (A116).[1] SKB held a number of patents on nicotine gum, all of which have expired.

---

[1] Citations in the form A### refer to the Joint Appendix filed with the United States Court of Appeals for the Second Circuit. Citations in the form CA### reference the Confidential Joint Appendix filed with the Court of Appeals. Citations in the form Pet. App. ## reference petitioner's appendices. The citation "Resp't App. A" refers to the respondent's appendix attached to this Opposition.

In 1992, as the SKB patents on the gum began to expire, SKB sought to extend its monopoly by pursuing FDA approval to sell Nicorette as an over-the-counter ("OTC") drug. (Pet. 7). As part of this process, SKB was required to submit its proposed labeling to the FDA. *See* 21 U.S.C. §355(b)(1)(F) and § 321(m); *see also Kordel v. United States*, 335 U.S. 345, 349-50 (1948). SKB's labeling included a user's guide and an audiotape. The user's guide and audiotape constitute "labeling" as defined by the FDA Act. 21 U.S.C. § 321(m); 21 C.F.R. § 202.1(l)(2); *Kordel*, 335 U.S. at 349-350.

The SKB user's guide describes the nature of nicotine addiction and contraindications for use of the gum (pp. 3-5); provides a stop smoking time-table (p. 6); explains how the gum works and how to use the gum (pp. 8-10, 11-12, and 20); answers questions about the product (pp. 17-19); advises quitters how to address the mental aspects of the addiction (pp. 3-4, 12-13, and 16); and provides support numbers for the American Medical Association, the American Cancer Society, and the like (back cover). (A80-93).

The SKB audiotape is entitled "Nicorette Usage Instructions." It contains a comparable discussion of reasons to quit smoking and strategies for quitting smoking by using the drug. Side A is entitled "How To Use Nicorette"; Side B is entitled "Tips To Help Make Quitting Easier." (A96-105).

The FDA approved Nicorette, including the user's guide and audiotape text, for OTC sale in 1996. (*Id.*). Under 21 U.S.C. § 355(c)(3)(D)(iii), SKB thereupon received an additional three years of market exclusivity for its OTC version of the gum. That exclusivity expired in February 1999. On April 21, 1998, near the end of this additional three-year, FDA-awarded monopoly on the OTC gum, SKB applied for copyright registrations on the text of its user's

guide and audiotape. (A78-79 and A94-95). On February 9, 1999, the same day SKB's FDA exclusivity expired, SKB applied for yet another copyright registration on the words and music on the tape. (A603-04).

B. Watson's Generic Nicotine Gum

The Hatch-Waxman Amendments to the FDA Act were enacted to enable lower-cost generic drugs to be brought to market faster, an outcome Congress determined was manifestly in the public interest. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997).

The Hatch-Waxman Amendments were the result of detailed Congressional balancing of the rights of drug innovators and the public's need to access lower priced generic drugs. Among other objectives, Congress sought to speed up the process of generic drug approval so as to introduce price competition promptly once the patents and exclusivity periods awarded to the original drug had expired. (Pet. App. 10a; *Mead Johnson Pharm. Group v. Bowen*, 838 F.2d 1332, 1333 (D.C. Cir. 1988)).

Watson applied to the FDA to sell a generic version of Nicorette gum in 1994. (A258). FDA required Watson to submit evidence that its generic gum product – including the user's guide and audiotape – would be "the same as" Nicorette. 21 U.S.C. § 355(j)(2)(A)(v); 21 C.F.R. § 314.94(a)(8)(iv). (A616; *see* CA447-52). Watson could not sell its generic gum without using FDA approved labeling. 21 U.S.C. § 355(a); *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 612-13 (1973).

Watson initially sought approval for audiotape text different from the SKB audiotape text. (A259). The FDA

rejected Watson's proposed text on the ground that it was not "the same as" the text used in SKB's audiotape. (A616, A259). Thereafter, Watson revised its audiotape text to be the same as the SKB audiotape text. Watson also submitted for approval a user's guide that had substantially identical text to that contained in the SKB user's guide.

FDA approved Watson's labeling in March 1999. (A259-60, A617).

C. The Preliminary Injunction

In August 1999, Watson launched its generic nicotine gum. The day Watson launched its product, SKB filed this suit in the United States District Court for the Southern District of New York. SKB contended that Watson's user's guide and audiotape text infringed SKB's copyrights and sought a preliminary injunction. (A441-42). The case was assigned to the Honorable Denny Chin.

The district court held a hearing on SKB's request for a preliminary injunction. Watson opposed the injunction primarily on the ground that any copying in its user's guide and audiotape had been necessary in order to comply with the FDA requirements, including specifically 21 U.S.C. § 355(j)(2)(A)(v).

Following the hearing, the district court received a letter from the FDA indicating that the FDA did not require a generic drug applicant's "behavioral support materials" to be identical to those of the original drug. (A618; Pet. App. 58a). The district court understood this letter to suggest that Watson had the ability to modify its user's guide and audiotape so that they would not be the same as to the SKB materials. (*Id.*)

Based on this understanding of the FDA's position, the district court granted the preliminary injunction. The court concluded that Watson had the ability to change its materials to make them non-infringing and that Watson should have made more of an effort to obtain approval of different text for its user's guide and audiotape. (A619).

D. The FDA Again Requires Watson To Copy SKB's Labeling

Following entry of the preliminary injunction, the district court stayed the action to permit Watson to seek FDA-approval of revised labeling. (A510-11). In September 1999, Watson submitted revised labeling to the FDA. The revised labeling was rewritten to avoid any claim of copyright infringement by SKB. (CA67-68). The labeling contained rewritten text, new graphics, a new layout, a unique style and an original format, and was different from the materials originally approved by the FDA and enjoined by the district court. (A619).

On November 23, 1999, after considering Watson's submission, the FDA rejected Watson's revised materials. The FDA instructed Watson to return to its originally approved text (which was identical to the SKB text and was the subject of the preliminary injunction). FDA provided Watson with a "mock-up" copy of Watson's originally approved text with brackets inserted to indicate the few words that FDA would permit Watson to change. (CA73-90).

Watson again revised its labeling, following the FDA's directions exactly. Where the FDA required identity, Watson's revised labeling is identical. Where the FDA allowed differences, Watson's revised labeling is different. The FDA approved Watson's revised labeling on December 27, 1999. Despite the limited changes, the text of Watson's

revised labeling remained substantially similar to SKB's labeling.

E. The District Court Refuses To Enjoin Watson's Revised Labeling

In December 1999, Watson moved to dissolve the preliminary injunction to permit it to sell gum using its revised labeling. Watson argued that, contrary to the court's original understanding, the FDA in fact required Watson to copy much of the SKB text verbatim and that an injunction was therefore unwarranted.

The district court held a hearing on Watson's request. The FDA attended the hearing and explained its position to the court. Thereafter, in a December 22, 1999 Memorandum Decision, the district court dissolved the injunction and permitted Watson to sell its gum using its revised labeling. (A614-28).

The district court recognized that unless Watson used the revised labeling, it could not market its gum. (Pet. App. 29a-30a). The court noted that Watson had been severely harmed by the injunction and that "the public has a stake in this controversy." (*Id.* at 32a). The court reasoned that the public would benefit from the introduction of generic competition to Nicorette gum. The court added that SKB "has not only enjoyed a monopoly for some fifteen years, but surely knew that someday a generic version" of its gum would reach the market. (*Id.*).

After carefully balancing all of the public and private interests, the court concluded that the public's interest in access to generic nicotine gum predominated. The court stated: "[t]he fact is that no generic version of Nicorette is likely to reach the market anytime soon, unless SKB's

arguments are rejected." (*Id.* at 34a). Therefore, the court dissolved the injunction and permitted Watson to sell its gum using the revised labeling. (*Id.* at 35a).

F. The Court Of Appeals Affirms The District Court And Dismisses SKB's Suit For Failure To State A Claim

SKB timely appealed the district court's dissolution of the preliminary injunction to the United States Court of Appeals for the Second Circuit.

The United States filed an *amicus curiae* brief supporting the district court's decision to dissolve the injunction. The United States' brief set forth its views on both the protection of copyright and the approval of generic drugs under the Hatch-Waxman Amendments.[2] The United States' brief also set forth the FDA's interpretation of the relevant statute and regulations.

The United States summarized FDA's position on the proper construction of the "sameness" provision in § 355(j) as follows:

> The Hatch-Waxman Amendments require that a generic drug have the same labeling as the labeling approved for the pioneer drug on which the generic is based. FDA has concluded that the statute's same-labeling provision [§355(j)(2)(A)(v)] *requires that the*

---

[2] The Second Circuit was thus fully apprised of the United States' position as to the copyright issues in the case. The United States' *amicus* brief noted the government's "compelling interest in the proper interpretation of copyright law." U.S. *Amicus* Br. at 3. Contrary to the suggestion in petitioner's brief, there is no need to seek input from the Registrar of Copyrights on this issue. The Second Circuit considered the United States' interests in proper copyright enforcement.

> *generic drug's labeling be identical.* The minor differences FDA allows under its interpretation of the different-manufacturer exception are carefully cabined to avoid suggesting any therapeutic difference between the pioneer and generic drugs.

U.S. Amicus Br. at 7, emphasis added.

On April 4, 2000, a unanimous panel of the United States Court of Appeals for the Second Circuit, in an opinion written by Chief Judge Winter, affirmed the district court's refusal to enjoin Watson's revised labeling. The court also concluded that SKB could prove no set of facts under which it would be entitled to relief on its copyright claim and hence directed dismissal of SKB's complaint.

After reviewing the statutory provisions governing the approval of generic drugs, the court of appeals found that FDA properly interpreted "the same as" in 21 U.S.C. § 355(j)(2)(A)(v) to require that the labeling of a generic drug be substantially similar to the labeling of the originally approved drug. The court noted that while "the same" need not necessarily mean "identical," the plain meaning of the statute and the legislative history of the Hatch-Waxman Amendments support the conclusion that the range of permissible differences is very small. (Pet. App. 12a-13a). Accordingly, the court of appeals found that the plain meaning of Section 355(j) required Watson's labeling to be substantially similar to SKB's.

The court of appeals harmonized the Hatch-Waxman Amendments with the Copyright Act based on the plain language of both statutes and the intent of Congress as evidenced by the two statutory schemes. The court reasoned that allowing a copyright claim to prevent the marketing of generic drugs would greatly frustrate the essential purpose of the Hatch-Waxman Amendments. By contrast, allowing

Watson to market its generic drug using the same labeling would not undermine the purposes of the Copyright Act.

The court noted that one of the fundamental purposes of the Hatch-Waxman Amendments was to expedite the introduction of generic drugs after the patents and exclusivity periods on the original drug had expired. (Pet. App. 10a). The statute requires a generic drug manufacturer to submit the same data that the original manufacturer supplied, with the exception of clinical testing. In particular, Congress specifically required a generic drug manufacturer to show that its labeling was "the same as" the labeling of the original drug, except for limited changes related to the identity of the manufacturer and the like. (*Id.* at 11a). Thus, the requirement that a generic drug copy the original drug's labeling is integral to the regime Congress created to ensure safety and efficacy of generic drugs while expediting their introduction into commerce. (*Id.*).

On the other hand, the court found that the purposes of the Copyright Act would not be harmed in the event SKB's copyright claims were to fail. The court noted that the FDA requires original drug manufacturers to submit original labeling and this creates a substantial motivation for manufacturers to prepare such labeling. In the court's view, "not one" drug developer would be deterred from creating labeling by the rejection of SKB's claim. (Pet. App. 17-18a). Harmonizing the two statutes, the court concluded it was obvious from the two statutory schemes that the Hatch-Waxman Amendments preclude a copyright claim on these facts. (Pet. App. 17a).

The court of appeals went to considerable lengths to emphasize that the decision did not undermine the incentive to create fostered by the Copyright Act and that its decision did not repeal SKB's copyright. (Pet. App. 16a-18a). The

court emphasized that, unless the copying is mandated by the Hatch-Waxman Amendments, original drug manufacturers in SKB's position retain the right to assert their copyrights. (Pet. App. 18a).[3]

REASONS FOR DENYING THE PETITION

I. THE DECISION BELOW PRESENTS NO ISSUE WARRANTING THIS COURT'S REVIEW

A. The Petition Presents No Conflict Or Important Question Of Federal Law

This is a case of first impression. (Pet. App. 44a). The court of appeals decision does not conflict with any decision of this Court or with any decision of another court of appeals.

The Hatch-Waxman Amendments and the Copyright Act have co-existed for over fifteen years. In that time, the question decided by the Second Circuit and presented here has apparently never arisen before. We are aware of no pending cases raising the same issue. Petitioner points to none.

---

[3] SKB failed to file a timely petition for reconsideration of the Second Circuit decision. Nearly two months after the decision, SKB filed a petition to recall the mandate and seek reconsideration. The Second Circuit denied the motions on July 10, 2000. On the same day, the FDA sent Watson a letter consistent with the interpretation expressed by the United States' *amicus* brief and applying that statutory construction mandated by the Second Circuit. (Resp't App. 1b). The letter required Watson to revise its labeling to be "the same as" the labeling for Nicorette.

As petitioner concedes, the issue presented in this case will not arise in most cases involving the approval of generic drugs. (Pet. 24, 25 & n.10). In most instances, generic drug labeling contains largely factual information. (Pet. App. 17a-18a & n.5). Labeling containing only dosing, indication, and safety data (the vast majority of the FDA's generic drug work) does not implicate the present copyright issue.

In construing Section 355(j), the court of appeals relied on the plain language of the statute, reviewed the legislative history, and harmonized the Copyright Act with the language of Section 355(j)(2)(A)(v). The court of appeals noted that the proper harmonization of the two statutes was obvious from the plain meaning and purposes of the statutes. (Pet. App. 17a).

As is apparent from petitioner's recitation of the facts, much of the uncertainty in this case arose as the FDA struggled to adapt to SKB's unprecedented attempt to use its copyright to stifle the generic drug regime created by the Hatch-Waxman Amendments. The FDA's position is now clear and is entirely consistent with the Second Circuit's decision. Review is unwarranted.

B. Petitioner's Efforts To Cast This Case As One Worthy Of Review Are Not Persuasive

Petitioner's arguments are based on the fundamentally inaccurate premise that the court of appeals' decision "repeals," "nullifies" or "voids" its copyright and that the decision therefore "erodes" the intellectual property rights and incentives of drug developers. In reality, the court below did none of these things.

The court of appeals made it clear that it was not "voiding" or "nullifying" SKB's copyrights and that SKB's

copyright interests were not repealed. The court specifically stated that drug companies in SKB's position retain a copyright that, if otherwise valid, may be asserted against copiers other than those whose copying is mandated by the Hatch-Waxman Amendments. (Pet. App. 18a ("We emphasize that we do not read the Hatch-Waxman Amendments to repeal other rights under the Copyright Act")). In contrast to petitioner's overblown hyperbole, the court of appeals was careful, limited, and measured in its harmonization of the two statutes. [4]

Likewise, the court carefully considered the potential harm to copyright holders and concluded that the risk its decision would impact an author's incentive to create new labeling was essentially non-existent. (Pet. App. 16a-18a). The court found it "simply not conceivable" that "even one" drug company would be deterred from creating the labeling needed to secure FDA approval for its drugs. As the court

---

[4] The assertion, in footnote 11 on page 28 of the Petition, that the Second Circuit's decision conflicts with another Second Circuit decision in *CCC Information Services, Inc. v. MacLean Hunter Market Reports, Inc.*, 44 F.3d 61 (2d Cir. 1994) or with *Practice Management Information Corp. v. AMA*, 121 F.3d 516 (9th Cir. 1997) is simply wrong. Further, intra-circuit conflicts, even when present, do not create grounds for certiorari. *Davis v. United States*, 417 U.S. 333, 340 (1974).

Moreover, there is no conflict here. Both *CCC* and *Practice Management* concluded that a copyright holder does not forfeit its copyright simply because a governmental body adopts the copyrighted work into positive law. Both cases recognize that while the copyright is not forfeited, it may become unenforceable in some circumstances and against some copiers. The Second Circuit's decision does not conflict with *CCC* and *Practice Management*. Here, the court found that SKB's copyright was not forfeited, but that the Hatch-Waxman Amendments limited the enforcement of the copyright against one, narrow class of copiers. In contrast, these cases relate to whether, when a copyright has been enacted into law, the copyright owner may still assert the copyright against infringers. There is no conflict with these cases.

noted in an analysis far more precise and rigorous than petitioner's, the labeling in question is prepared in large part to secure FDA approval for drugs. That incentive will continue to motivate creative expression in drug labeling, irrespective of the outcome of this case.

The Second Circuit's measured approach demonstrates that there is no significant copyright issue this Court needs to address. The copyright issues raised by the petitioner were carefully considered and correctly decided below.

II. THE COURT OF APPEALS' DECISION CORRECTLY APPLIES THIS COURT'S PRECEDENT REGARDING HARMONIZATION OF TWO FEDERAL STATUTES

A. The Decision Below Properly Harmonized The Copyright Act With The Plain Language Of Section 355(j)

The court of appeals properly construed Section 355(j)(2)(A)(v) and harmonized that statute with the Copyright Act. In so doing, the court of appeals followed the precedent of this Court and correctly read Section 355(j) in light of its plain meaning. The court's decision is consistent with the purpose and history of the relevant statutes as well as the position of the FDA. There is no error in the court's methodology or result. There is no reason for this Court to grant a writ of certiorari.

In cases involving statutory construction, the analysis begins with the language of the statute. *Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438 (1999). Where the statutory language provides a clear answer, the analysis ends there as

well. *Id.*; *see also Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 254 (1992).

Here, the court of appeals determined – and SKB does not dispute – that Watson's user's guide and audiotape fall squarely within the plain meaning of the term "labeling" in 21 U.S.C. § 321(m). (Pet. App. 11a-12a). Next, the court found that the plain meaning of "the same as" provision of Section 355(j) requires the generic drug labeling to be identical to the original labeling approved by the FDA. (*Id.* at 12a-14a). This plain language construction was entirely consistent with the court's review of the legislative history and purpose of the Hatch-Waxman Amendments. (*Id.* at 14a-16a). The court's construction is also in accord with the FDA's interpretation of the statute.

Having found that the plain language of Section 355(j) requires a generic drug applicant effectively to copy the originator's labeling, the court next considered the provisions of the Copyright Act. The court expressly applied the canon of statutory construction that, "where two laws are in conflict, courts should adopt the interpretation that preserves the principal purposes of each." (Pet. App. 14a) (*citing Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1347 (Fed. Cir. 1999)).

The court reviewed the purposes and objectives of both statutes. The court concluded it was obvious from the plain meaning of the statutes that a copyright claim could not lie against a generic drug manufacturer that was required to copy a drug label under Section 355(j) in order to secure approval for a generic drug. (Pet. App. 17a). The court found that this outcome best effectuated the purposes of the Hatch-Waxman Amendments and did not undermine the incentive to create that the Copyright Act fosters.

The court noted that the Hatch-Waxman Amendments were designed to expedite the time to market for generic drugs by streamlining the approval process without compromising public health and safety. (Pet. App. 15a-16a). To that end, generic drug manufacturers are required to submit evidence that their product, including the relevant labeling, is "the same as" the original drug. *See* 21 U.S.C. § 355(j)(2)(A)(v). Thus, the identity of the generic labeling is an integral part of the statutory scheme to hasten the approval of generic drugs.

At the same time, the court reasoned that its decision would not impair drug manufacturers' incentive to create drug labeling. (Pet. App. 17a). The court noted that the labeling in question was needed to secure FDA approval for the original drug and that therefore original drug manufacturers continued to have a substantial economic incentive to prepare the labeling. (*Id.*).

The court of appeals' decision was careful, thorough, and based expressly on the plain language of the statutes in question. The court applied the canons of statutory construction petitioner improperly accuses it of ignoring. The decision is well reasoned and correct. There is no need for further review by this Court.

B. Petitioner Identifies No Error In The Court Of Appeals' Decision

Petitioner contends that, notwithstanding the plain language of the statute, the court of appeals was obligated to contort Section 355(j) so that petitioner could use its copyright to prevent the very same generic competition that Congress plainly intended to encourage. The text of the statute and the legislative history do not support petitioner's

position, and so petitioner instead invokes general canons of construction – repeals by implication are disfavored and courts should try to harmonize two statutes when that is possible. (Pet. 22-23).

The court of appeals did not ignore or misapply these canons of construction. The court specifically referred to such canons and explicitly applied them. (Pet. App. 14a). The court's construction of the two statutes to preclude a claim of copyright infringement when Section 355(j)(2)(A)(v) requires copying reflects an appropriate harmonization of the two statutes based on the intent of Congress. In *FDA v. Brown & Williamson Tobacco Corp.*, this Court noted that the "classic judicial task of reconciling many laws enacted over time, and getting them to 'make sense' in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute." __ U.S. __, 120 S. Ct. 1291, 1306 (2000); *United States v. Fausto,* 484 U.S. 439, 453 (1988). The court of appeals carefully considered the relevant canons of construction in reaching this conclusion.

Petitioner agrees "it is reasonable to presume," as the court of appeals did, that in using the term "the same as" in Section 355(j), "Congress envisioned identical copying of the factual information contained in the pioneer drug labeling." (Pet. 23). Petitioner contends that Section 355(j) should be construed to mandate copying of *factual* material but not *original, creative* material. (*Id.*). This argument lacks merit.

First, the statutory language contradicts petitioner's construction. The statute requires a generic drug to have the same labeling as the original drug. The term "labeling" is defined in 21 U.S.C. § 321(m). Under the statute, a generic drug's labeling must be the same as the original drug's

labeling. There is no foundation for petitioner's *fact* vs. *creative material* distinction in the statute.

Second, petitioner's construction contradicts the FDA's construction of the statute. The FDA has concluded that the original labeling and the generic labeling must be the same because differences in labeling tend to suggest to consumers therapeutic differences between the original and generic drugs. The FDA has nearly 20 years of experience regulating nicotine gum and over 60 years of experience regulating addictive drugs. The FDA's interpretation was made by its Center for Drug Evaluation and Research, which comprises physicians, pharmacists, and other professionals experienced in labeling addictive prescription and over-the-counter drugs before they are offered to the public.

Recognizing its expertise in this area. courts accord the FDA wide latitude in the application of the drug labeling requirements. *See Henley v. FDA*, 77 F.3d 616 (2d Cir. 1996). Undoubtedly, the FDA's discretion includes the right to develop its position in response to new circumstances. That evolution occurred in this case and the FDA's position represents the considered judgment of its labeling professionals and is wholly in accord with the Second Circuit's decision.

Finally, petitioner concedes that pioneer drug applicants will continue to prepare labeling for their drugs, notwithstanding the court of appeals' decision, as the labeling is necessary for FDA approval of the underlying drug. (Pet. 26-27). Petitioner contends the labels will be "dry and clinical" rather than "creative" unless the court of appeals is reversed. (Pet. 28). This argument is unpersuasive. Petitioner's argument overlooks that SKB and other drug manufacturers have a substantial financial incentive to make

their product, labeling, and packaging attractive, useful, and user-friendly to consumers.[5]

Petitioner has failed to raise any significant question regarding the court of appeals' decision. The court below carefully applied the relevant canons of construction and there is no error in that decision.

---

[5] Petitioner argues that the court of appeals' conclusion, "if taken literally," would require a generic drug manufacturer to appropriate, for example, the performance rights of the artists who performed for the SKB audiotape. (Pet. at 27). However, the FDA has ample flexibility to determine that the actors on the audiotapes need not be identical. The FDA is primarily concerned with the text and tenor of the labeling. For example, if a certain actor were unavailable to make a new audiotape, the FDA could certainly approve an audiotape orated by a different actor provided it had the same text and tenor of the original audiotape. The Court need not grant certiorari to consider a wild hypothetical that will never come to pass.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

Barry S. White
James K. Stronski
Charles J. Raubicheck
Deena P. Levy
FROMMER LAWRENCE
& HAUG LLP
745 Fifth Avenue
New York, NY 10151
(212) 588-0800

Joseph P. Lavelle
Counsel of Record
Matthew J. Moore
Laura C. Miller
HOWREY SIMON ARNOLD &
WHITE, LLP
1299 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 783-0800

Counsel for Respondents
Watson Pharmaceuticals, Inc.,
Watson Laboratories, Inc., and
Circa Pharmaceuticals, Inc.

AUGUST 2, 2000

APPENDIX

APPENDIX A-LETTER FROM THE FOOD AND DRUG ADMINISTRATION TO WATSON PHARMACEUTICALS, INC.

Watson Laboratories, Inc. July 10, 2000
Attn: Joyce Anne DelGaudio
33 Ralph Avenue
P. O. Box 39
Copiague, NY 11726-0030

Dear Madam:

This is in reference to your abbreviated new drug applications for Nicotine Polacrilex Gum, approved on March 15, 1999.

Consistent with the position of the FDA as articulated in the United Sates' amicus curiae brief filed in SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharmaceuticals, Inc. on January 19, 2000 and with the Second Circuit decision in that case issued on April 4, 2000, we ask that you revise your "Audiotape" and "User's guide" to be "the same" as the labeling for the reference listed drug, Nicorette® Gum.

Prepare and submit to your approved application in accordance with 21 CFR 314.70(b), 12 copies of the revised final printed labeling for the "User's guide" and 12 copies of the revised final printed labeling for the "Audiotape" along with 4 copies of the revised finished audiotapes (2 for each application). This supplement should be marked "Supplement-Expedited Review Requested."

If you have any questions or if you need further information, please contact Kim Dettelbach, Associate Chief Counsel at

301-827-1148 or Charlie Hoppes, Division of Labeling and Program Support at 301-827-5846.

Sincerely yours,

William Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research